

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of educational messages on the prevention of respiratory infectious diseases, with emphasis on Covid-19 based on the developed parallel process model, on risk control responses in diabetic middle-aged people

Protocol summary

Study aim

Evaluating the effect of educational messages containing response effectiveness, self-efficacy and perceived threat (perceived sensitivity/severity), risk control response, and fear control responses in diabetic middle-aged

Design

Clinical trial with one control group and two intervention groups, with parallel groups, one-way blind, randomized on 240 diabetic middle-aged people. All eligible individuals are arranged according to the national code, then three blocks are used, each block as Randomly, one is in the control group and the other two are in the intervention group and continue in the same way

Settings and conduct

This study was performed on 240 diabetic middle-aged people in Shahinshahr health centers, which were divided into two groups of intervention and control, in which 80 people are in each group. The receiver is unaware and the study is one-way blind

Participants/Inclusion and exclusion criteria

Entry requirements 1- Middle-aged (30-60 years) diabetic should be covered by selected health centers 2- Satisfaction for the company 3- Literacy 4- Persian language and citizen of Iran 5- Smart phone 6- Ability to use mobile smart phone 7- History of not being infected with Quid-19 Exit conditions 1- Not wanting to continue participating in the study 2- Leaving the area covered by the health center 3- Malfunction or lack of mobile phone access 4- Having any disease, which is not able to continue participating in the study

Intervention groups

Middle-aged two groups receive training messages based on the components of response effectiveness, self-efficacy, and perceived threat for 1 month (two training messages per week) via WhatsApp or Soroush channel.

The control group did not receive a message and only training. They routinely receive health personnel

Main outcome variables

Perceived Sensitivity & Intensity/Self-Efficacy/Response Efficiency/ Fear/Fear Control & Risk Control Response

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210609051525N1**

Registration date: **2021-06-29, 1400/04/08**

Registration timing: **retrospective**

Last update: **2021-06-29, 1400/04/08**

Update count: **0**

Registration date

2021-06-29, 1400/04/08

Registrant information

Name

Dena Ghafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3080

Email address

dena.ghafari@hlth.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-26, 1400/04/05

Expected recruitment end date

2021-06-26, 1400/04/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of educational messages on the prevention of respiratory infectious diseases, with emphasis on Covid-19 based on the developed parallel process model, on risk control responses in diabetic middle-aged people

Public title

The effect of education on the prevention of acute respiratory disease

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Middle-aged (30-60 years) diabetics should be covered by selected health centers To be satisfied to participate in the study Be literate. Be Persian-speaking and Iranian citizens. Have a smart phone. Be able to use mobile phones to subscribe and use the content of WhatsApp and Soroush groups. Do not have a history of Quid 19

Exclusion criteria:

Reluctance to continue participating in the study Leaving the area covered by the selected health center, for any reason Mobile phone failure or lack of access Having any illness, in which the participant is unable to continue participating in the study

AgeFrom **30 years** old to **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **240****Randomization (investigator's opinion)**

Randomized

Randomization description

After obtaining the necessary permits, and ensuring the validity of the research tool, sampling will be done in such a way that initially diabetic middle-aged people in Shahinshahr will be considered. After reviewing the entry criteria, all eligible people are arranged according to the national code, then triple blocks are used in such a way that the first three national codes form a block, each of which is randomly one in the control group and two Others are in the intervention group and continue in the same way.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

Street address

Faculty of Health, Isfahan University of Medical Sciences, Hezar Jerib St, Isfahan

City

isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-06-26, 1400/04/05

Ethics committee reference number

IR.MUI.RESEARCH.REC.1400.126

Health conditions studied**1****Description of health condition studied**

Infectious respiratory diseases

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Diabetes

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Response efficiency and perceived self-efficacy and threat (perceived severity and sensitivity)

Timepoint

Before the intervention and one week after the intervention

Method of measurement

questionnaire

Secondary outcomes

empty

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shm@phc.mui.ac.ir

Intervention groups

1

Description

The first group of intervention: are middle-aged people who, based on the results of the pre-test, have a perceived threat score higher than average. They will. This group completes the questionnaires again one week after the intervention.

Category

Behavior

2

Description

The second group of intervention: are middle-aged people whose perceived threat score is lower than the average score. This group receives both messages related to perceived threat (perceived sensitivity / severity) and messages of response efficiency and self-efficacy for one month (They will receive two training messages per week via the virtual channel. This group completes the questionnaires again one week after the intervention.

Category

Behavior

3

Description

Control group: The group that is considered as a control group does not undergo any educational intervention by the researcher. Simultaneously with the first and second groups, post-test will be performed in this group as well. It should be noted that at the end of the study, in order to observe ethics in research, educational messages will be placed in the control

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahinshahr Health Center

Full name of responsible person

dr masud poor mehrab

Street address

9 west, taleghani, shahin shahr

City

shahin shahr

Province

Isfahan

Postal code

8164969459

Phone

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Hagh Joey javan mard

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

dena ghafari

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries

Contact

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Ph.D.

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable